DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA CERTIFIED MAIL

WARNING LETTER

FLA-03-26

March 25, 2003

Daniel M. Navarro, President
Advanced Radiation Measurements, Inc.
601 N.E. Emerson, Street
Port St. Lucie, Florida 34983

Dear Mr. Navarro:

During an inspection of your establishment located in Port St. Lucie, Florida on February 3-4, 2003, Investigator R. Kevin Vogel of the Food and Drug Administration (FDA) determined that your establishment manufactures radiation beam scanners. These products are used by medical physicists to measure the radiation emitted from an accelerator to capture data used to develop a treatment plan for patients requiring radiation therapy and are devices, as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (Act).

The investigator documented significant deviations from the Quality System (QS) Regulation, Title 21, Code of Federal Regulations (CFR), Part 820 and the Medical Device Reporting regulations, Title 21, CFR, Part 803. These violations cause the devices you manufacture to be adulterated within the meaning of Section 501(h) and misbranded within the meaning of Section 502(t)(2) of the Act.

Quality System Regulation

The investigator noted the following violations of the QS regulation:

1. Your firm failed to establish and conduct quality audits to verify that the quality system is effective as required by 21 CFR 820.22. You failed to establish and maintain audit procedures and you admitted to the investigator that you were not sure what a quality audit was supposed to cover. (FDA 483, Item #s 8 & 9).

2. Your firm failed to validate processes whose results cannot be fully verified by subsequent inspection and test according to established procedures as required by 21 CFR 820.75. Structural testing conducted as part of your firm's software validation, and software validation of the Scan Test used to conduct finished product testing was not documented, and your firm failed to validate the Eprom burn-in process (FDA 483, Item #1).

3. Your firm failed to establish and maintain procedures for implementing corrective and preventive action and corrective and preventive activities have not been documented as required by 21 CFR 820.100(a) & (b). Corrective and preventive actions including: the analysis of sources of quality data, investigations of causes of nonconformities, actions needed to correct or prevent recurrence of nonconforming product and other quality problems, and verification of corrective actions have not been documented (FDA 483, Item #2).

4. Your firm failed to document evaluations of nonconforming product as required by 21 CFR 820.90(a). Specifically, in-process rejects are not documented (FDA 483, Item #4).

5. Your firm failed to establish and maintain procedures for complaint handling and to maintain consumer complaints as required by 21 CFR 820.198(a). Consumer complaints received by mail or telephone are not documented and there are no procedures established for handling complaints (FDA 483, Item #s 3 & 12).

6. Your firm failed to evaluate and select potential suppliers and contractors on the basis of their ability to meet specified requirements as required by 21 CFR 820.50(a)(1). Your firm failed to assure that your contract electronic manufacturer has appropriate electrostatic discharge (ESD) reduction procedures and appropriate solder process validation (FDA 483, Item #5).

7. Your firm failed to establish procedures to control the design process of the device and your design history file does not demonstrate the device design was developed following an approved design plan and design control requirements as required by 21 CFR 820.30(a) & (j). Your firm failed to document all appropriate areas of design control including design plan, design review, design validation, and risk analysis (FDA 483, Item #s 6 & 7).

8. Your firm's device master record (DMR) failed to include or refer to the location of the quality assurance procedures and specifications as required by 21 CFR 820.181(c). Specifically, your firm lacks written procedures covering finished product testing (FDA 483, Item #11).

Medical Device Reporting (MDR) Regulations

The investigator noted that there was a failure to comply with a requirement prescribed under Section 519 of the Act as follows:

9. Your firm failed to establish and maintain written MDR procedures as required by 21 CFR 803.17 (FDA 483, Item #13).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Additionally, no premarket submissions for Class III devices to which the QS regulation deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the steps you have taken to correct the noted violations, including: (1) the time frames within which the corrections will be completed, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

Emma Singleton
Director, Florida District